

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:
To: Kaufman, Annette
NCI
EPN BG RM 4032

Exempt #: 11642

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The purpose of this project is to understand how new tobacco product advertisements are perceived and influence product beliefs. In recent years, the tobacco industry has strategically focused marketing efforts on products that do not emit secondhand smoke (e.g. Snus). Under Food and Drug Administration regulation of tobacco, claims such as 'reduced harm' and 'modified risk' are prohibited, so tobacco companies can not explicitly advertise products as a less addictive or safer alternative to cigarettes. To circumvent these

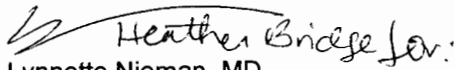
Original Request Received in OHSR on: 10/23/2012

Responsible NIH Research Investigator(s): Annette Kaufman, NCI

OHSR review of your request dated Mon, Oct 22, 2012 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Confidentiality Agreement
- Reliance
- Amendment
- Other

Note: Office Person HB Admin Assist. CB


Lynnette Nieman, MD

Director, OHSRP
Title

10/25/2012
Date

Domestic/International:
Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

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